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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,409	02/21/2002	Francine Baldo	219928US0	5630

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EXAMINER
YU, GINA C

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/078,409	Applicant(s) BALDO ET AL.	
	Examiner Gina C. Yu	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The enablement for methods of prevention of skin aging lacks support from the applicant's specification or prior art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

The enablement test requires require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation.

See MPEP § 2164.01, reciting In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). To determine whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue", following factors are considered: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in

the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, at 737

In this case, the burden of enabling the prevention of skin aging (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such conditions. In the instant case, the specification does not provide guidance as to how one skilled in the art would go about preventing those patients susceptible to aging within the scope of the presently claimed invention. Nor there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing the skin conditions among the patients. Finally, given the fact that skin aging is a natural phenomena which is caused by intrinsic and extrinsic factors, examiner views that a routineer in the current state of art would need undue experimentation to determine the efficacy of the claimed invention. The specification fails to enable "prevention", and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method for the prevention of skin aging.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-5, 9, 14-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al. (US 6124364) ("Breton").

Breton teaches aging skin treatment formulations comprising resveratrol (3,4',5-trihydroxystilbene) and polyols such as butylenes glycol or glycerin. See Example 2. See instant claims 1-3, 5, 6, 9, 14, and 20. The reference also teaches the hydroxystilbenes of instant claim 2. See col. 4, lines 6 – 30. The reference teaches that the amount of hydroxystilbenes can range from 0.001-10 % by weight, and that the amount depends on the desired effect. See col. 4, lines 36 – 40. The polyols of the example formulations range from 1-7 % by weight. The reference also teaches the oily phase of instant claims 14 and 15. See col. 4, line 56 – col. 5, line 18. The additives are taught in col. 5, lines 51 – 65.

While the weight ratio of the polyol and resveratrol in the example formulations differs from the recited limitation of the instant claims, examiner notes that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Breton, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. It would have been obvious to a skilled artisan that lowering the concentration of an active component would be economically advantageous and/or meet the consumer demand for less effective yet cheaper products.

2. Claims 6, 10-13, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton as applied to claims 1-5, 9, 14-17, and 20 above, and further in view of Ribier et al. (US 5658575) ("Ribier").

Breton, discussed above, fails to teach the lamellar liquid crystal emulsion composition and the method of making thereof.

Ribier teaches cosmetic compositions comprising an oil-in-water emulsion containing nano-scale oily globules coated with lamellar liquid crystal are dispersed in an aqueous phase. See abstract. The reference suggests adding cosmetic actives such as antioxidants, anti-ageing agents, and phytanetriol. See col. 4, lines 28 – 51. The reference teaches the method of making the composition, and teaches that the aqueous phase of the composition comprises

an active agent in a dissolved state. See col. 1, lines 51 – 60; col. 4, lines 19 – 51; col. 6, lines 1 – 16; instant claims 18 and 19. The reference teaches that the nanoemulsion of the invention exhibits good skin penetration when applied topically. See col. 2, lines 36 – 60.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Breton by incorporating the resveratrol composition of Breton by incorporating the actives in the nanoemulsion as motivated by Ribier, because of an expectation of successfully producing an anti-aging cosmetic composition with good penetration of active ingredients.

3. Claims 1-9, 14-17, and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pillai et al. (US 6358517 B1) ("Pillai").

Pillai teaches a non-aqueous topical composition comprising resveratrol and 2 % of ethanol by weight. See Example 9. The reference teaches that emollients, which may be polyols, can be used in the amount ranging from 0.5-50% by weight. See col. 3, lines 57 – 63. The reference particularly teaches using polyethylene glycol and butylenes glycol as emollients and penetration enhancers, respectively. See col. 4, lines 8 – 18; instant claims 5 and 6. The reference teaches using 0.00001 – 10 % by weight of resveratrol. See col. 2, lines 16-64.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Pillai by adding the polyols as motivated by the reference because of an expectation of successfully

producing a non-aqueous topical composition with enhanced moisturization and/or penetration.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner